UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
SOUTHERN DIVISION AT CHATTANOOGA

ANGELA MONTGOMERY, Plaintiff, vs **WYETH**, f/k/a American Home Products Corp.; **AHP SUBSIDIARY HOLDING CORPORATION** f/k/a Wyeth-Ayerst Laboratories Company; **WYETH PHARMACEUTICALS, INC.** f/k/a Wyeth-Ayerst Pharmaceuticals, Inc. Defendants.	Case No.: 1:05-cv-00323 Collier/ Lee

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION TO EXCLUDE OR LIMIT THE TESTIMONY OF KEITH ALTMAN

A. Mr. Altman is a Fact Witness and is Not Being Offered as an Expert.

Plaintiff is not offering Keith Altman as an expert witness and he will not be offering expert opinions. In his report in this case (attached as **Exhibit A**). Mr. Altman stated:

> I am not an "expert witness" in the sense of C.R 26, because I will be testifying as to fact, not opinions, although I will use technical expertise to summarize those facts. I have technical expertise to provide summary testimony. This notice allows defendants sufficient time to cross-examine me on my findings and summaries.

Notwithstanding this explicit disclosure that Mr. Altman is not being offered as an expert witness, Wyeth has moved pursuant to *Daubert* to exclude the expert opinions of Keith Altman and has challenged his qualifications as an expert. However, at the same time, Wyeth states that it has no objection to limiting Mr. Altman to testifying as to "non-expert foundational testimony concerning summaries of evidence under Rule 1006." Consistent with his report, that is

precisely how plaintiff intends to offer Mr. Altman at trial. Fed. R. Evidence 1006 (Summaries) provides:

> The contents of voluminous writings, recordings, or photographs which cannot conveniently be examined in court may be presented in the form of a chart, summary, or calculation. The originals, or duplicates, shall be made available for examination or copying, or both, by other parties at reasonable time and place. The court may order that they be produced in court.

Given Wyeth's statement that it has no objection if Mr. Altman provides non-expert foundational testimony concerning summaries of evidence, Wyeth apparently does not challenge Mr. Altman's qualifications and technical abilities to testify in that capacity. Accordingly, there should be no dispute concerning Mr. Altman's technical qualifications.[1] Mr. Altman's experience and credentials are detailed in his report, pp. 1, 2, his CV, and in his Declaration, pars. 1-10, 15, and 21, all of which are attached hereto, as **Exhibits A**, **B**, and **C**, respectively.

B. Wyeth Has Stipulated to the Accuracy of Specific Data in Mr. Altman's Summaries.

In another diet pill case where plaintiff's counsel was involved, Wyeth stipulated to the accuracy of the data contained in various specified fields in Mr. Altman's summary reports. *See* attached Stipulation, **Exhibit D**. In addition, Wyeth has had Mr. Altman's summaries, has taken his depositions on multiple occasions, and has not raised any challenge to the accuracy of the data. *See* Altman Declaration, pars. 3, 11, 13

[1] Mr. Altman's credentials include over 25 years of experience working with complex database information. In that capacity, he has extensive experience with pharmaceutical safety data, and with Wyeth's safety surveillance databases in particular. Preparation of the summaries requires the type of technical expertise that Mr. Altman uses daily and that he has been using for over two decades. Mr. Altman, therefore, is well qualified to testify at trial concerning his methodology for creating the summaries from Wyeth's safety surveillance databases, and he should be able to explain what they are based on.

C. Evidence of Adverse Events is Relevant.

Wyeth claims evidence concerning adverse event reports is irrelevant. This Court should reject this argument because it has no basis in pharmaceutical products liability law. Mr. Altman's summary charts in this case provide a picture of what Wyeth would see when it looked at its own safety surveillance database. Altman Declaration, par. 12. Notice of adverse events are functionally equivalent to "case reports," and as such are certainly relevant to this case as it provides evidence of what Wyeth knew and when Wyeth knew about certain risks and adverse events that are relevant to this case and which were reported in association with its diet pills. The adverse events also are relevant under the Code of Federal Regulations pertaining to when warnings are required on pharmaceutical products.

As the Tennessee Supreme Court stated in the case *McDaniel v CSX Transportation, Inc.*, 955 S.W. 2d 257, 261 (Tenn. 1997) case reports are relevant to an important issue in this case. They are relevant for determining whether an association existed between Pondimin and pulmonary hypertension. The court stated:

> Case reports are not epidemiological studies, but merely reports of individuals who have been exposed to an agent and then report symptoms associated with the disease. Case reports usually precede the institution of formal epidemiological research, although they can be important in determining whether an association exists between an agent and a disease or defect. For example, the medical community became aware of the association between the drug, Thalidomide, used by pregnant women as a sedative and birth defects in their children as a result of case reports.

In addition, the Code of Federal Regulations requires a pharmaceutical company to issue a warning when, based on its safety surveillance data or other information, it has "reasonable

evidence of an association" between the use of its drug and a serious adverse event. Proof of causation is not required. 21 CFR § 201.57(e)[2].

In fact, Wyeth's internal documents, and testimony by Wyeth personnel, which will be offered as evidence at trial, show that Wyeth personnel prepared a draft label change for Pondimin concerning the risk of pulmonary hypertension. This proposed change in the label was based in large part on information contained in Wyeth's adverse event database concerning patients who developed pulmonary hypertension after exposure to Pondimin.[3]

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D. **Evidence of Valvular Heart Disease is Relevant.**

Wyeth also claims that Mr. Altman's summaries pertaining to valvular heart disease are irrelevant. Plaintiff has addressed in detail the relevance of valvular heart disease to this case in a separate brief. *See* Plaintiff's Motion to Allow Evidence of All Risks and Benefits of Pondimin and Redux, which is being filed by plaintiff, contemporaneously with this opposition.

E. Wyeth's Critiques of Mr. Altman's Summaries Go to Weight, Not Admissibility.

Wyeth's remaining critiques of Mr. Altman's summaries[4], addressed below, go to the weight not the admissibility of the proffered testimony.

[2] The "Warning" section of the Pondimin product label was silent about pulmonary hypertension, although the FDA regulations require a warning when the company becomes aware of an association between use of its drug and a serious adverse effect. 21 CFR § 201.57(e). The regulation states in part: "Labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."

[3] Unfortunately, the evidence at trial will show that the proposed label change was never implemented based on concerns that management had that disclosure of these risks for Pondimin had "implications" concerning another almost identical diet pill medication (Redux) which was pending FDA approval.

[4] Given Wyeth's acknowledgment that Mr. Altman can testify as a fact witness concerning his summaries of Wyeth's safety surveillance database, it is not clear whether Wyeth's other critiques require a response. However, because this is not clear, plaintiff will respond briefly.

To understand the issues raised by Wyeth, this Court should understand what Mr. Altman did to prepare the summaries, how he documented his work, and what he provided to Wyeth.

Mr. Altman began to analyze Wyeth's voluminous Clinical Drug Safety Surveillance System ("CDSSS") data that had been produced by Wyeth approximately nine years ago. At the onset of the diet pill litigation, the CDSSS data was provided to Mr. Altman approximately in November 1998 by the New Jersey-Pennsylvania Diet Drug Group (NJ 405)—a group of attorneys with diet pill cases pending in New Jersey. Mr. Altman was asked to take the data as provided and convert it into a format which could be used by the attorneys and experts working on diet pill cases. That data is contained in a CD-Rom, attached to Mr. Altman's report. Mr. Altman extracted these data files and loaded the files into Microsoft Access for ease of use. As additional information became available, Mr. Altman supplemented his work product.

In October, 2004, Mr. Altman was provided with an extract of Wyeth's "$S^{3"}$ adverse event system. This is the system currently in use by Wyeth. He extracted various data from this database, which covers adverse event reporting (ADE's) from the period of November, 1999 to approximately September 2004. Mr. Altman attached as exhibits to his report the S^3 data produced to him as well as his working set of the merged narratives. He also worked with Wyeth's S^3 database in several other litigations. In February, 2006 in the Children's Advil case, *Madden v. Wyeth* (N.D.Texas), the judge ordered that the plaintiff be provided supervised access to Wyeth's S^3 system at the Wyeth Collegeville, Pennsylvania facility. Mr. Altman was selected to visit the Wyeth facility for this purpose in order to learn about that database.

Mr. Altman also performed additional analysis of the CDSSS, S^3, and FDA adverse event databases. He attached to his report the results of these analyses as well as a description of the methodologies used.

In addition to the electronic files, Mr. Altman has had the opportunity to review paper adverse event files that contained not only MedWatch adverse event forms, but, in addition, printouts from CDSSS as maintained at Wyeth. Using this and accepted technical principles and methodology, and the descriptions of the data files as provided by Wyeth, Mr. Altman was able to determine the meaning of the fields in the database (attached in the CD-Rom) as well as the relationship between the various tables. All of the tables are related by the report number field, which is the manufacturer's control number. Using this field it is possible to assemble all of the data related to one report. Mr. Altman checked the data to eliminate duplicate reports.

As a result of the above, Mr. Altman is able to respond to requests to provide various reports from the CDSSS data in a reliable and efficient format. When asked to generate reports, he does not employ subjective analysis to decide whether a given report contains any particular adverse event. Rather, he relies on the classifications used by Wyeth in its database. He also stated in his report that he may refer to the FDA Adverse Event Data Spontaneous Reporting System which is publicly available through the National Technological Information System (NTIS). Mr. Altman attached the raw FDA data as an exhibit to his report. Mr. Altman also attached summary reports from the CDSSS that he prepared as Summary Exhibits, upon which other experts herein will rely. He also provided in his report a complete list of these summary exhibits which he compiled and verified.

All of the work that Mr. Altman prepared in this case in creating summaries is completely verifiable by Wyeth. Wyeth has had access to the summaries and has taken Mr. Altman's deposition three times. To date, Wyeth has identified only a single instance where Mr. Altman misread text that indicated an adverse event report was a duplicate of another. On each of

several occasions when Wyeth has deposed Mr. Altman, Wyeth has been provided a disk with his complete working files. *Id*., par. 10.

Wyeth claims that Mr. Altman should not be allowed to testify about the meaning of fields within the CDSSS database, claiming that he has no foundation for such testimony. To the contrary, Mr. Altman's knowledge of the company's database is based upon his attendance at depositions of several Wyeth witnesses[5] with knowledge about these issues. He has attended multiple depositions of Wyeth witnesses in several different Wyeth litigations. Part of the basis for his specific knowledge of the Wyeth safety databases and the fields within those databases comes from these depositions. He has also reviewed manuals and other technical materials. The company has also provided data maps to Mr. Altman. In fact, at one of Mr. Altman's depositions attorney Eric Alexander, a lawyer for Wyeth in this case, showed data maps to Mr. Altman and asked him questions about the data maps. *Altman Declaration,* par. 15.

At no time has Wyeth or Wyeth's counsel ever demonstrated that any statements Mr. Altman has made concerning the contents of any fields, the relationship between any fields, or the relationship with any tables is incorrect or that Mr. Altman's methodology is unreliable. Wyeth has had the charts and data prepared by Mr. Altman for more than four years and has deposed him multiple times on his work, as noted above. *Id*., par. 3. At Mr. Altman's depositions Wyeth lawyers have spent substantial amounts of time questioning him about his work with the databases.

As to the contents of the S^3 database, Mr. Altman has worked with this data in five different litigations involving Wyeth. In the case of *Madden v. Wyeth*, the court ordered that Mr.

[5] For example, as Mr. Altman explained in his report (at page 4), Mr. Altman was able to learn about Wyeth's safety surveillance database, as pertains to the diet pill litigation, in part by attending the deposition of Mr. Thomas Udicious in May of 1998. Mr. Udicious worked in Wyeth's Global Safety Surveillance department. His title was Director, Information Management.

Altman visit Wyeth's facility to meet with Wyeth personnel so that he could learn about the S^3 database. At the hearing in that case, Mr. Altman made a live demonstration to the court of both the Wyeth S^3 database and the FDA data. At Wyeth's offices, Mr. Altman had extensive discussions concerning Wyeth's adverse event system and he worked with Wyeth personnel to insure that the S^3 adverse event data was extracted correctly. *Id.*, par. 16.

Wyeth claims that Mr. Altman did not review the underlying adverse event reports that are the underlying source of the data in the database. The summary charts that Mr. Altman created are simply reports of what is contained in the various databases. Those databases were created based on Wyeth personnel reviewing the underlying reports, and Mr. Altman therefore did not find it necessary to also review the underlying reports in order for him to create a summary of the database. Altman Declaration, par. 18. Indeed, Wyeth routinely generated reports from the same database without going back to the underlying adverse event reports.

As to the meaning of the data fields in the CDSSS and S^3 databases, Mr. Altman has been provided adequate materials by Wyeth, and as stated above, he has attended discovery depositions of Wyeth personnel and also has personally spoken with Wyeth personnel as noted above.

With the exception of identifying a single report included in the charts that was a duplicate, Wyeth has never demonstrated that anything that Mr. Altman has prepared or stated concerning its data is incorrect. There are no subjective determinations by Mr. Altman. Moreover, Wyeth has the capability of verifying every summary for correctness. At each of Mr. Altman's depositions, Mr. Altman provided Wyeth with all of the underlying data that he used to prepare the charts along with his working data sets. There is no "opinion" regarding the

relationship of the tables. They are exact mathematical computations that are correct or incorrect. *Id*., par. 16.

Wyeth also criticizes Mr. Altman's work claiming that it is dependant on the accuracy of the underlying data. Wyeth is required by the FDA to maintain a safety surveillance database and Wyeth does so and relies on its accuracy. Wyeth entered all of the data into the CDSSS and S^3 database and relied upon these entries in the routine course of business. Mr. Altman did nothing more than show what was in the database that Wyeth created. Wyeth would have had to depend on the same data in the same way to look for potential safety signals. *Id*., par.20.

CONCLUSION

For the reasons stated herein, the motion to exclude or even limit the testimony of Keith Altman should be denied.

DATED this 7th day of January, 2008.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I do hereby certify that on 7th day of January 2008, I electronically filed the foregoing document with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to the following:

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